90-658

No. _____

In The

Supreme Court of the United States

October Term, 1990

GREEN DRUGS and RAYMOND S. KAUFFMAN,

Petitioners,

v.

UNITED STATES OF AMERICA,

Respondent.

PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

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QUESTION PRESENTED

1. Whether the United States Court of Appeals for the Third Circuit erred when it affirmed the Trial Court's judgment which held the petitioners strictly liable when the Trial Court in its Bench Opinion found inadvertent mistake/error, no malice or illegal gains, no negligence on the petitioners' part and there is no federal statute, legislative history or congressional intent in the Government's cause of action that states anything about strict liability?

PARTIES TO THE PROCEEDING

The parties to the proceeding below were the same as in the caption.

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PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

Petitioners respectfully pray that a writ of certiorari issue to review the judgment and opinion of the United States Court of Appeals for the Third Circuit.

OPINIONS BELOW

The judgment and opinion of the United States Court of Appeals for the Third Circuit (App. 1-13) is reported at 905 F.2d 694 (3rd Cir. 1990). The order of the Third Circuit denying rehearing in banc (App. 14) is not reported. The bench opinion of the U.S. District Court for the Eastern

District of Pennsylvania filed September 29, 1989 (App. 15-19) is not reported.

JURISDICTION

The decision of the U.S. Court of Appeals for the Third Circuit was entered on June 15, 1990. The U.S. Court of Appeals for the Third Circuit denied Rehearing In Banc on July 26, 1990. The time for filing a petition for writ of certiorari is therefore October 23, 1990. This petition for writ of certiorari is filed within ninety days of that order in compliance with Rule 13. This Court's jurisdiction is invoked under 28 U.S.C. Section 1254.

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

21 U.S.C., SECTION 827(a)(b) – Records and reports of registrants. (See App. 20)

21 U.S.C., SECTION 842(a)(5) – Prohibited acts B, unlawful acts. (See App. 21)

Comprehensive Drug Abuse Prevention and Control Act of 1970:

P.L. 91-513; 84 Stat. 1236, SECTION 307(a)(1)(2)(3), (b)(1) – Records and Report of Registrants, SECTION 308(c)(1)(2) (See App. 22-23)

Drug Abuse Control Amendments of 1965: P.L. 89-74; 79 Stat. 226, SECTION 2(d)(1) – Findings and Declaration. (See App. 24)

Remington's Practice of Pharmacy A Treatise Incorporating the Harrison Narcotic Law, The Act of December 17, 1914. (See App. 25-26)

Legislative History

For Legislative history and purpose of Pub.L. 91-513, see 1970 U.S. Code Cong. and Adm. News, p. 4588(7) and p. 4590 – Records and Reports. (See App. 27)

Comprehensive Drug Abuse Prevention and Control Act of 1970 – P.L. 91-513, see p. 1437.

Pharmacist's Manual – An Informational Outline of the Controlled Substances Act of 1970 – pg. 8 – Records pg. 22-23 – Inventory Requirements. (See App. 28)

STATEMENT OF THE CASE

The basis for Federal Jurisdiction in the District Court for the Eastern District of Pennsylvania is under 28 U.S.C., Section 1345 and 21 U.S.C., Section 842.

Petitioner seeks review of an order of the United States Court of Appeals Third Circuit with Judgment and Opinion entered June 15, 1990, Rehearing Denied July 26, 1990. The Judgment was for a total of $6,000.00 for civil liability of violations of three counts of 21 U.S.C., Section 827(a) and (b) and 21 U.S.C., Section 842(a)(5) in failing to account for certain quantities of Schedule II drugs, 2,752 Preludin 75 mg tablets, 4,798 Percodan tablets and 1,902 Percocet tablets.

From May 5, 1985 to October 21, 1986, the time period relevant to the question presented in this petition there was absolutely nothing expressed or implied in the *Comprehensive Drug Abuse Prevention and Control Act of 1970* – P.L. 91-513, see p. 1437 which relates strict liability

to the Act. This Act among other things governs how pharmacies control their Schedule II drugs. There was nothing in 21 U.S.C., Section 801, et al which relates strict liability to the practice of pharmacy and their control of Schedule II drugs. At the time of filing this Writ of Certiorari there is still nothing which relates strict liability to the practice of pharmacy and their control of Schedule II drugs other than the Opinion of the Third Circuit affirming the Lower Court's decision.

In the instant case, the U.S. Attorney commenced a proceeding in Civil Court for alleged shortages of three Schedule II drugs. The petitioners filed an answer and counterclaim. The basis of the counterclaim was that the DEA, during the relevant time period, failed to act on the petitioners' reporting of a drug shortage on DEA form 106. The respondent's motion to strike petitioners' counterclaim was granted. A waiver trial commenced on August 7, 1989. The Judge issued a Bench Opinion in favor of the respondent. However, the Trial Judge stated in his Bench Opinion that there was no negligence, or criminal wrongdoing but inadvertent error/mistake. The Court found strict liability. On October 4, 1989, petitioners' Notice of Appeal was filed. The Court of Appeals without argument wrote an Opinion affirming the Lower Court's decision. The three member panel's decision was unanimous. Petitioners then filed a Petition for Rehearing. Although the rehearing was denied, it is interesting to note that one of the members of the original panel voted for a rehearing.

REASONS FOR GRANTING THE WRIT

The courts below have so far departed from accepted and usual course of judicial proceedings as to call for an exercise of this Court's power of supervision. There are special and important reasons for the Court to grant this Writ of Certiorari.

If a private citizen would file a civil claim alleging a cause of action such as strict liability and there was nothing in the statutes to allow this particular cause of action, the court would instruct the individual that the theory of law was not applicable. The court would also state that it is a legislative determination to have a legal theory on the books.

However, in the instant case, the Government has gone to the courts and asked them to rule on a cause of action, strict liability, which is not in the applicable statutes or acts. The courts in this case have improperly taken away the legislative process by imposing its will. The purpose is to bypass the legislature which would be a lengthy and not necessarily a successful process for the government. Although, the intent of the Government is to prevent legal drugs from entering illicit channels, the end does not justify the means. Courts interpret the laws made by the legislature. The respondents have asked for a wide interpretation of the legislative history of the *Comprehensive Drug Abuse Prevention and Control Act of 1970*. The interpretation by the lower courts in the instant case is outside the borders of even the widest reading.

Strict liability does not apply to pharmacists, doctors or dentists. The pharmacist in a retail pharmacy has a dual role. He or she is both a professional, providing a

service and a business person. However, the pharmacist's primary role is their performance of a professional service to the community.

In the instant case, the Third Circuit Court of Appeals in its Opinion outlines a group of cases that are very much distinguishable from this case.

Courts in a number of states have already addressed the issue of strict liability. However, these cases are not necessarily on point with the instant case. At least the cases that are brought forth in this petition have relevancy to the topic of pharmacy and strict liability and are not stretched to the point where they have to bring in "migratory bird and hand grenade cases" as presented by the Court in its Opinion.

Since the decision by the U.S. Court of Appeals Third Circuit has nationwide implications, it is important to look at some cases around the country that have addressed the issue of strict liability as it pertains to pharmacists.

The California State Court of Appeals extensively addressed the issue of pharmacists and strict liability and stated:

> "Where primary objective of a transaction is to obtain or perform a service, rather than acquire title to or use of a product, doctrine of strict liability is inapplicable." *Murphy v. E.R. Squibb & Sons, Inc.*, 156 Cal.App.3d 589, 202 Cal.Rptr. 802 (1984).
>
> "Persons providing service for guidance of others must satisfy only a duty of reasonable care under given circumstances and cannot be held responsible for injury in the absence of

negligence or intentional misconduct." *Id. Murphy,* page 802.

"Retailer distributor of drug could not be held strictly liable for plaintiff's injuries allegedly attributable to her mother's ingestion of drug diethylstilbestrol while her mother was pregnant with her, in view of the fact that product supplied by retailer distributor was incidental to its primary purpose involving performance of professional service." *Id. Murphy,* page 802.

In *Murphy,* the Court, in making its determination of no strict liability for pharmacists, examines how other states addressed the issue. The Court looks at cases from Florida, North Carolina, New York, New Jersey, Texas and Wisconsin.

"The foregoing cases illustrate a manifest reluctance by the courts to extend strict liability to parties offering or involving medical treatment or services. Moreover, where a few courts have seemingly been inclined towards extending strict liability, they have followed a more traditional approach in deferring to said concept as a legislative function." (See *Hoven v. Kelble,* supra, 79 Wis.2d 444, 256 N.W.2d 379, 392), *Id. Murphy,* page 809.

"Perhaps first and foremost, it bears nothing that claims against pharmacists for the sale of defective drugs based on the doctrine of strict liability have been met with unequivocal rejection in other jurisdictions. In *McLeod v. W.S. Merrell Co., Div. of Richardson-Merrell,* (1965) 174 So.2d 736, the Florida Supreme Court gave short shrift to a claim of strict liability against a druggist for selling an injurious drug. It concluded that retail druggists, as in that particular instance, were excepted from liability pursuant to the Restatement Second of Torts, section

402A, comment k. Additionally, the Florida Court indicated that it considered sufficient safeguards already existent for the consumer, and that it was unnecessary to analyze the filling of a prescription as the rendering of a service as opposed to the supplying of a commodity." *Id. Murphy,* page 806.

The Court in *MURPHY* states: "The logic motivating the policy of not extending strict liability or liability without fault to providers of services was cogently set forth by our Supreme Court in *Gagne v. Bertran,* supra, 43 Cal.2d at page 489, 275 P.2d 15: 'The services of experts are sought because of their special skill. They have a duty to exercise the ordinary skill and competence of members of their profession, and a failure to discharge that duty will subject them to liability for negligence.' " *Id.* page 807.

The Pennsylvania Superior Court held "that a pharmacist could not be held strictly liable as a supplier of prescription drug." *Coyle by Coyle v. Richardson-Merrell, Inc.,* 538 A.2d 1379, 372 Pa. Super. 118, appeal granted 551 A.2d 215, 520 Pa. 588, Pa. Super (1988)

The Pennsylvania Superior Court states "this attempt at distinguishing their case overlooks, however, our conclusion, in Makripodis regarding any type of strict liability imposition upon pharmacists: '[W]e can perceive no benefit to be derived from the imposition of strict liability upon the pharmacist who properly dispenses a prescription drug upon the prescription of a duly licensed physician.' Makripodis, supra 523 A.2d at 379. It is clear, therefore, that a pharmacist will not be held strictly liable under section 402A of the Restatement (Second) of Torts as a supplier in the chain of distribution of a prescription drug." *Id. Coyle,* page 1381.

California as well as other states were able to find no strict liability as it applies to pharmacists because there was no federal law to the contrary. No case which has been put forth by either the appellants or the appellee finds strict liability as it relates to pharmacists.

In the instant case, the effect of the lower courts extending strict liability to pharmacists would have a extremely far reaching and negative effect.

In the instant case, there is no strict liability in the statutes or acts. If the Court would examine the definition section of the Controlled Substance, Drug Device and Cosmetic Act, it would see that strict liability is not present. In West Federal Practice Digest 3d, Volume 112 *Descriptive Word Index P-Z*, strict liability does not list pharmacists or the applicable statutes and acts involving this case.

In the Opinion of the U.S. Court of Appeals Third Circuit, *U.S. v. Green Drugs*, 905 F.2d 694, 698 (3rd Cir. 1990), the court refers to Senator Griffin's comments about strict recordkeeping. Strict recordkeeping does not equal strict liability. Nowhere does it say in definitions in any of the statutes or acts in this case that these terms are synonomous. Strict liability is never even mentioned. Senator Griffin's comments on the new recordkeeping feature for inventory of all controlled dangerous substances at least once every two years is both misleading and inaccurate.

Prior to the *Comprehensive Drug Abuse Prevention and Control Act of 1970*, inventories were required every year and not every two years as is now required by the Act.

"Remington's Practice of Pharmacy 1956 incorporating the Harrison Narcotic Law, pages 1457, 1458:

Registration – Persons already registered must on or before July 1 of each year file application in the same manner for the renewal of their registration.

Inventories – An inventory on the reverse of Form 678 is required for each class except Classes 1 and 2."

Inventories prior to 1970 were done annually and mailed in to the appropriate agency. Inventories taken after the 1970 Act are done every two years and are kept on file in the pharmacy but are not mailed. (Refer to Pharmacist's Manual – An Informational Outline of the Controlled Substances Act of 1970 – pg. 8 – Records pg. 22-23 – Inventory Requirements. (See App. 28).

The 1970 Act by increasing the amount of time in between inventories from one to two years is actually making the system more liberal and less tight. It is very important to realize that an inventory is not equal to an audit. An inventory is the amount or quantity of drugs on hand at a particular time. Since the law requires a biennial inventory, the accounting is done once every two years. The inventory does not check the disposition of drugs, only the quantity.

The audit reconciles records of receipt and disposition with actual inventory. The applicable statutes and acts do not require audits, only inventories. Audits make the system tight, inventories do not. In addition, records prior the 1970 Act had to be kept for three years and after the Act only for two years.

When the petitioner fills a prescription, the drug is counted by hand. Over a period of time, there will be human error resulting in discrepancies. The petitioners' expert at trial testified that 5% or less is an acceptable error. In the instant case, quantity of drugs that the respondent alleged was missing was drastically reduced at trial with numbers ranging from 5% to 1% deviation. The reasons for the decrease in numbers are first, a DEA Agent who testified at trial stated that he destroyed prescription records of the petitioners without getting permission or informing petitioners, second, another DEA Agent misread DEA order form 222 mistaking Percodan demi for Percodan, third, the agent that misread the form also did not take into account broken tablets, fourth, the DEA Agent as he testified at trial did not use all available records in the audit as required by the Warrant for Inspection, (using all available records, state and federal would have drastically reduced the shortages) and fifth, prescription misfilings which were produced by the petitioners (even the trial judge stated that that even happens to legal documents). The petitioners had all the required records, proved the quantities much less than respondents alleged, and within proper and customary percentage of deviations as testified by petitioners' expert.

The trial judge still found the discrepancies substantial.

The petitioners operate a busy pharmacy that serves Center City and many of the city hospitals. The store is opened from 8:00 a.m. to 12:00 midnight (16 hours per day), seven days a week, three-hundred and sixty-five (365) days a year. Only a very few pharmacies in the City of Philadelphia are opened these hours. The pharmacy is

surrounded by four large hospitals with active emergency rooms that are opened 24 hours a day, seven days a week. Therefore, his prescription volume is large. The trial judge saw numbers/discrepancies that he thought were high and did not appreciate a recognized reasonable percentage deviation as testified by the appellants' expert. Strict liability means that regardless of the deviation the pharmacy is liable and that does not make sense when pharmacists are counting tablets by hand over a period of a year and a half in this case. It is interesting to note, that after the trial was over when the petitioners counted a sealed bottled of Dilaudid, Schedule II drug, there was a shortage of a few tablets which was reported to the DEA. This was not the only shortage the DEA had noted from this particular manufacturer. With strict liability, the pharmacist would be liable regardless of fault.

The Court in its Opinion refers to the statement of Senator Dodd and tries to infer that strict procedures involving drugs means or equates to strict liability. The learned, respected and experienced Senator knew that in order to get a law on the books, it had to be passed by the legislature. If Senator Dodd wanted strict liability to be applied, in the controlled substances act or in any of the legislation affecting pharmacists, he would have to introduce a Bill asking specifically for strict liability to apply. We know that never happened and we can infer that he never wanted that to happen.

Respondent's, in their brief to the U.S. Court of Appeals, Third Circuit reviewed three cases. The petitioners distinguish the respondent's three cases that they cite in their brief.

First, *Blue Chip Stamps v. Manor Drug Stores*, 421 U.S. 723, 756 (1975) (Powell, J., concurring). The only relationship this case has with the case at bar is the word "drug" in its caption. *Blue Chip Stamps* deals with trading stamps, Securities Exchange Act of 1934, fraud and anti-trust. Nowhere in this entire case is there a mention of the Controlled Substances Act or drugs. The respondents are trying to relate Congressional Intent with a totally unrelated case. It is interesting to note, that in the two other cases that respondents mention in their brief, there is no mention of the Securities Exchange Act in these drug cases. The respondents are trying to match "apples and oranges" when they relate the case at bar with *Blue Chip Stamps*.

Second, the respondents then cite *United States v. Greenberg*, 334 F. Supp. 364, 366 (W.D. Pa. 1971). This case is a drug case which relates to the validity of an administrative inspection warrant. Petitioners do not contest this case since we agree with its findings. In the case at bar, the Appellants never questioned the warrant and never tried to suppress anything at trial. On the contrary, petitioners were trying to bring all their records to the attention of the Court. In addition, the instant case is civil with never any criminal proceedings or a hint of any criminal wrong doing. *Greenberg* is a criminal case.

Third, *United States v. Williams*, 416 F. Supp. 611, 614 (d.D.C. 1976). This is a civil case in which the

> "defendant/pharmacist had engaged in a course of business conduct in willful and callous disregard of the law and regulations regarding controlled substances when he knew, or should

> have know, that he was in violation of Controlled Substances Act by filing forged and photocopied prescription, by failing to maintain complete and accurate records with respect to receipt and distribution of certain drugs, and a filing prescriptions when he knew or should have known that many of them had not been issued in the course of legitimate medical practice; that pharmacist would be assessed civil liability in the amount of $35,000.00."

Absolutely none of the things mentioned above were done by the petitioners as testified by both the respondents and petitioners and as concluded by the Judge in the case at bar. All of the petitioners' reasonable commercial practices were totally legitimate and not as related in *Williams*. If the instant case had any relationship to *Williams*, the petitioners would not be in the Supreme Court.

Strict liability would impose a very heavy burden on legitimate pharmacists. There are already sufficient civil and criminal laws in place to take care of Pharmacists that violate federal or state laws.

Strict liability is a cause of action which is so important that where it is applicable it is clearly stated in the law. It is not a cause of action that comes in through the closed back door, but is stated in Black Letters.

CONCLUSION

Petitioners respectfully request that the Writ of Certiorari be granted.

Respectfully submitted,

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APPENDIX

United States Court of Appeals

FOR THE THIRD CIRCUIT

No. 89-1850

UNITED STATES OF AMERICA

vs.

GREEN DRUGS and
RAYMOND S. KAUFFMAN, Appellants

(D. C. Civil No. 89-0173)

ON APPEAL FROM THE
UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT
OF PENNSYLVANIA

Present: MANSMANN, SCIRICA and SEITZ, *Circuit Judges*

JUDGMENT

This cause came on to be heard on the record from the United States District Court for the Eastern District of Pennsylvania and was submitted pursuant to Third Circuit Rule 12(6) April 2, 1990.

On consideration whereof, it is now here ordered and adjudged by this Court that the judgment of the said District Court, entered August 9, 1989, be, and the same is hereby affirmed. Costs taxed against the appellant. All of the above in accordance with the opinion of this Court.

ATTEST:

/s/ M. Elizabeth Ferguson
Chief Deputy Clerk

June 15, 1990

App. 2

Filed: June 15, 1990

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 89-1850

UNITED STATES OF AMERICA,

vs.

GREEN DRUGS and
RAYMOND S. KAUFFMAN,
Appellants

Appeal from the United States District Court
for the Eastern District of Pennsylvania
(D.C. Civil No. 89-0173)

Submitted Under Third Circuit Rule 12(6)
April 2, 1990

Before: MANSMANN, SCIRICA, and SEITZ,
Circuit Judges

(Filed June 15, 1990)

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OPINION OF THE COURT

MANSMANN, *Circuit Judge.*

In this appeal from a judgment assessing fines against a retail pharmacy and its owner, we are faced with the question of whether strict liability may be imposed for civil violations of the recordkeeping provisions of the Comprehensive Drug Abuse Prevention and Control Act, 21 U.S.C. §§ 801-971. The defendants argued, and the district court found, that the audit shortages – though substantial – resulted through inadvertence and human error. We conclude that the district court correctly ruled that the Act provides for liability without fault and will thus affirm.

I.

In October of 1986 the Drug Enforcement Administration, acting pursuant to an administrative inspection warrant, conducted an investigative audit of Green Drugs, a Philadelphia retail pharmacy, and its owner and manager, Raymond Kauffman, a registered pharmacist.[1]

[1] At trial the government presented evidence that Green Drugs attracted DEA's attention because it was one of the state's largest purchasers of several Schedule II controlled substances.

DEA investigators reviewed Green Drugs' records and stock, and noted that the pharmacy's receipt records accounted for more quantities of drugs than its dispensing records and inventory showed. Specifically, the investigators found shortages of 4,798 Percodan tablets, 1,902 Percocet tablets, and 2,753 Preludin tablets.

The government commenced this civil action with a three-count complaint, alleging that the defendants' failure to keep complete and accurate records of each drug violated the recordkeeping provisions of the Comprehensive Drug Abuse Prevention and Control Act, popularly known as the Controlled Substances Act, 21 U.S.C. §§ 827(a), (b) & 842(a)(5). The government sought a $25,000 civil penalty for each count.

At trial, the government presented corrected shortage figures: 1,698 Percodan tablets, 1,697 Percocet tablets, and 2,752 Preludin tablets. The defendants challenged the government's computation of the shortages contending that the deficiencies were minor, considering the large quantities of drugs processed by the pharmacy, and were due to human error and "inadvertent mistake." The defendants further argued that, as a matter of law, they could not be held liable because the recordkeeping provisions do not provide for strict liability.

The district court entered judgment in favor of the government. Accepting Kauffman's testimony, the court found that the shortages in the pharmacy's inventory were "inadvertent and innocent" and that the defendants acted in good faith. The court stated, however, that Congress had "imposed strict liability on retail pharmacists to account for Schedule II substances," and "decreed that

good faith is not a defense to inaccurate record keeping." The district court took into account the defendants' innocent motives and corrective measures before assessing a $6,000 fine, $2,000 for each count. The pharmacy and its owner appeal.

We have jurisdiction to review the final order of the district court under 28 U.S.C. §1291. The question presented on appeal is whether a civil violation of the recordkeeping provisions of the Act may be found and punished by a fine where the shortages are due to human error and no intent to violate the statute has been shown. The defendants would add, " . . . and where no illegal gains have been realized." Although the issue has received some mention in cases decided under the statute, *United States v. Williams*, 416 F. Supp. 611, 614 (D.D.C. 1976); *United States v. Barbacoff*, 416 F. Supp. 606, 610 (D.D.C. 1976), it is apparently one of first impression before the Courts of Appeals. Because the matter involves application and interpretation of legal precepts, our standard of review is plenary. *United States v. Engler*, 806 F.2d 524, 431 (3d Cir. 1986), *cert. denied*, 481 U.S. 1019 (1987); *Dent v. Cunningham*, 786 F.2d 173, 175 (3d Cir. 1986).

II.

Every registrant under the Controlled Substances Act engaging in the "manufacture, distribution, or dispensing of controlled substances" is required to "make a complete and accurate record of all stocks thereof on hand."[2] 21

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[2] The statute sets forth exceptions which are not applicable here.

U.S.C. §827(a)(1). Section 827(a)(3) likewise requires the registrant to maintain "a complete and accurate record of each . . . substance manufactured, received, sold, delivered, or otherwise disposed." *Id.* §827(a)(3). Such records must be maintained in strict accordance with regulations promulgated by the Attorney General and be available for inspection and copying by authorized officials for at least two years. *Id.* §827(b). Failure to maintain the requisite records constitutes a violation of 21 U.S.C. §842(a)(5),[3] and subjects the offender to civil or penal penalties, depending on whether the act was committed knowingly, *Id.* §842(c). "Inadvertent" mistakes due to sloppy recordkeeping subject pharmacies and owners to fines; a "knowing" violation subjects them to criminal sanctions of imprisonment, fines or both.

In tone and tenor, the Act's recordkeeping provisions mirror other food and drug legislation that Congress has enacted. The Supreme Court has upheld strict liability prosecutions under such statutes, where legislative history has provided for strict regulation.

Illustrative is *United States v. Balint*, 258 U.S. 250 (1922), where the defendants were indicted for violating the Narcotic Act of 1914, which made it unlawful "for any person to sell, barter, exchange, or give away" certain drugs, Act of Dec. 17, 1914, ch. 1, §2, 38 Stat. 785, 786

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[3] Section 842(a)(5) provides: "It shall be unlawful for any person . . . to refuse or fail to make, keep, or furnish any record, report, notification, declaration, order or order form, statement, invoice, or information required under this subchapter or subchapter II of this chapter[.]" 21 U.S.C. § 842(a)(5).

(repealed 1939). The district court dismissed the indictment because it did not charge that the defendants knew the drugs to be illegal, even though the law did not specifically make such knowledge an element of the offense. The Supreme Court reversed.

"[I]n the prohibition or punishment of particular acts," the Court reasoned, the legislature may "in the maintenance of a public policy provide 'that he who shall do them shall do them at his peril and will not be heard to plead in defense good faith or ignorance.' " *Id.* at 252 (quoting *Shevlin-Carpenter Co. v. Minnesota*, 218 U.S. 57, 70 (1910)). The Court noted examples found in regulatory measures in the exercise of the government's police power where the underlying purpose of the statute is centered on the advancement of some social purpose rather than the punishment of the crime.

In *Balint*, the Court determined that the congressional purpose of the Narcotic Act was "to require every person dealing in drugs to ascertain at his peril whether that which he sells comes within the inhibition of the statute, and if he sells the inhibited drug in ignorance of its character, to penalize him." *Id.* at 254. With respect to the traditional rule making scienter a requisite element of every crime, the Court declared that there is a modification of this rule where the purpose of the statute would be obstructed by such a requirement.[4]

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[4] The Supreme Court relied on *Balint* to explain the justification for the heightened standard of liability under pure food legislation:

(Continued on following page)

Later, in 1943, the Supreme Court adopted a similar analysis in *United States v. Dotterweich*, 320 U.S. 277 (1943), involving a conviction under a provision of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §331(a). The law imposed misdemeanor penalties for "[t]he introduction or delivery for introduction into interstate commerce of any food [or] drug . . . that is adulterated or misbranded." *Id.* The Court upheld the conviction, with Justice Frankfurter writing:

> The prosecution to which Dotterweich was subjected is based on a now familiar type of legislation whereby penalties served as effective means of regulation. Such legislation dispenses with the conventional requirement for criminal conduct – awareness of some wrongdoing. In the interest of the larger good it puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger.

Dotterweich, 320 U.S. at 280-81.

In determining the central issue in *Dotterweich* – whether the Act's penal sanctions could be levied against

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> The usual rationale for such statutes is that the public interest in the purity of its food is so great as to warrant the imposition of the highest standard of care on distributors – in fact an *absolute standard* which will not hear the distributor's plea as to the amount of care he has used. Cf. *United States v. Balint*, 258 U.S. 250, 252-253, 254. His ignorance of the character of the food is irrelevant.

Smith v. California, 361 U.S. 147, 152 (1959) (emphasis added) (dictum).

corporate officers – the Court examined the legislative history of the law, which revealed the congressional desire to "enlarge and stiffen the penal net" for the distribution of misbranded or adulterated drugs. *Id.* at 282.

On initial scrutiny, the recordkeeping provisions of the Controlled Substances Act, like the provisions of the statutes reviewed in *Balint* and *Dotterweich*, appear to fall within the "expanding regulatory area involving activities affecting public health, safety, and welfare," where it need not be shown that the alleged offender committed a willful violation. *United States v. Freed*, 401 U.S. 601, 607 (1971). The defendants, of course, urge a narrow reading – that because the Act does not specifically describe strict liability, it cannot be imposed. On this point, we are guided by the Supreme Court's statement that, in construing even criminal statutes,

> The canon in favor of strict construction is not an inexorable command to override common sense and evident statutory purpose. . . . Nor does it demand that a statute be given the "narrowest meaning"; it is satisfied if the words are given their meaning in accord with the manifest intent of the lawmakers.

United States v. Brown, 333 U.S. 18, 25-26 (1948) (citations omitted), *quoted in United States v. Moore*, 423 U.S. 122, 145 (1975).

Thus, as did the Supreme Court in *Balint* and *Dotterweich*, we must look to the legislative history of the governing law to determine if Congress intended strict regulation.

III.

Our starting point is, of course, the text of the statute itself, which plainly shows an absence of the scienter requirement for civil violations of the recordkeeping provisions. The mere failure or refusal to comply with the recordkeeping requirements is a violation of 21 U.S.C. §842(a)(5), a civil offense subjecting the offender to a maximum penalty of $25,000, 21 U.S.C. §842(c)(1). On the other hand, one who is charged with, and found to have committed, a "knowing[ ]" violation of section 842(a)(5) is subject to a criminal sanction of imprisonment of up to one year or a fine of not more than $25,000 or both, for the first offense. *Id.* §842(c)(2)(A).[5] Congress, therefore,

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[5] Section 842(c), the penalty provisions, reads in relevant part:

> (1) Except as provided in paragraph (2), any person who violates this section shall, with respect to any such violation, be subject to a civil penalty of not more than $25,000. . . .
>
> (2)(A) If a violation of this section is prosecuted by an information or indictment which alleges that the violation was committed knowingly and the trier of fact specifically finds that the violation was so committed, such person shall, except as otherwise provided in subparagraph (B) of this paragraph, be sentenced to imprisonment of not more than one year or a fine of not more than $25,000, or both.
>
> (B) If a violation referred to in subparagraph (A) was committed after one or more prior convictions of the offender for an offense punishable under this paragraph (2), or for a crime under any other provision of this subchapter or subchapter II of this

(Continued on following page)

plainly differentiated between civil and criminal violations of the recordkeeping provisions, implementing notably different standards of fault.

To determine whether Congress sought to regulate strictly the recordkeeping of drug inventory requires a broader examination of the accompanying legislative materials. The recordkeeping provisions of the Act are but a part of the comprehensive legislation enacted to combat the growing problem of drug abuse and drug trafficking in the United States. H.R. Rep. No. 1444, 91st Cong., 2d Sess. ___, *reprinted in* 1970 U.S. Code Cong. & Admin. News 4566, 4567. Indeed, the opening provisions of the statute offer a legislative finding that "[t]he illegal importation, manufacture, distribution, and possession and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people." 21 U.S.C. §801(2).

The legislative history reveals congressional concern to reduce the diversion of drugs from the legitimate course of commerce into illegal channels. 116 Cong. Rec. 996 (1970) (statement of Sen. Dodd). Congress thus sought measures to monitor the drug transactions of registrants, who with authority to dispense drugs, have the greatest access to controlled substances, and therefore,

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(Continued from previous page)

> chapter or other law of the United States relating to narcotic drugs, marihuana, or depressant or stimulant substances, have become final, such person shall be sentenced to a term of imprisonment of not more than 2 years, a fine of $50,000, or both.

21 U.S.C. §842(c)(1),(2).

the greatest opportunity for diversion. *See United States v. Moore*, 423 U.S. 122, 135 (1975). *See also* 1970 U.S. Code Cong. & Admin. News at 4569. Moreover, the Act was crafted to "continue[ ], and strengthen[ ]" then existing laws regarding recordkeeping and inventory. *Id.* at 4590. As to the recordkeeping provisions specifically. Senator Griffin commented:

> Other features of the bill aim at preventing diversion by *requiring strict recordkeeping*. Those who handle or manufacture controlled dangerous substances, with few exceptions, are required to maintain detailed records of receipts and disbursements. . . . Failure either to keep the records or make them available for inspection will subject the violator to severe penalties including forfeiture of his supply of controlled dangerous drugs.
>
> A new recordkeeping feature added by the bill is the requirement for an inventory of all controlled dangerous substances at least once every 2 years. This seemingly simple provision should prove to be a valuable aid in stopping diversion before it gets out of hand. . . . Subsequent *drug accountability audits will not deal in approximations, but rather in very precise figures.*

116 Cong. Rec. at 998 (statement of Sen. Griffin) (emphasis added).

Thus, a reading of the statutory text and history makes clear that Congress intended strict compliance with the recordkeeping provisions, with strict liability to attach for civil violations. On this issue, the disposition of the district court is correct in all respects.

We find further support in the analysis of the strict liability statute we utilized in *United States v. Engler*, 806

F.2d 425 (3d Cir. 1986), *cert. denied*, 481 U.S. 1019 (1987). The defendants in *Engler* were charged with unlawfully selling protected wildlife in violation of the Migratory Bird Treaty Act (MBTA), 16 U.S.C. §§703, 707(a), (b). We relied on the teachings of *Freed* and *Dotterweich* to uphold the strict liability provisions of the MBTA, over objection that the statute's lack of a scienter requirement failed due process protections.[6]

It is important to emphasize that in the present case, the government commenced a civil action against the pharmacy and the owner seeking fines, unlike *Balint*, *Dotterweich*, and *Engler*, which involved severe criminal sanctions as well as constitutional challenges to the mode of liability. Those cases present stronger (yet failed) arguments against the statutory strict liability scheme than what is made in this appeal.

The defendants further argue that the result we enunciate here would allow the government to hold virtually any pharmacy liable for the most minor infraction even where the greatest care has been exercised and good faith demonstrated. This is a consequence that Congress likely accepted in enacting the Act,[7] and perhaps should

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[6] Congress has since amended 16 U.S.C. § 707(b) to require that the offender act "knowingly." Emergency Wetlands Resources Act of 1986, Pub. L. No. 99-645, § 501, 100 Stat. 3582, 3590.

[7] In *Dotterweich*, the Supreme Court addressed a similar consequence of hardship under the Federal Food, Drug, and Cosmetic Act, stating:

(Continued on following page)

be considered together with the broad discretion the district court has in assessing fines. In any event, the shortages of the tablets in the present case were not insignificant, and the principles set forth in *Dotterweich* require that we heed the congressional mandate providing for strict accountability of drug inventory.

IV.

For the aforementioned reasons, the judgment of the district court will be affirmed.

A True Copy:

Teste:

Clerk of the United States Court of Appeals for the Third Circuit

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(Continued from previous page)

> Hardship there doubtless may be under a statute which thus penalizes the transaction though consciousness of wrongdoing be totally wanting. Balancing relative hardships, Congress has preferred to place it upon those who have at least the opportunity of informing themselves of the existence of conditions imposed for the protection of consumers before sharing in illicit commerce, rather than to throw the hazard on the innocent public who are wholly helpless.

Dotterweich, 320 U.S. at 284-85.

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 89-1850

United States of America

vs.

Green Drugs & Raymond Kauffman,

Appellants

SUR PETITION FOR REHEARING

Present: HIGGINBOTHAM, *Chief Judge*,
SLOVITER, BECKER, STAPLETON, MANSMANN,
GREENBERG, HUTCHINSON, SCIRCA, COWEN,
NYGAARD, ALITO and SEITZ, *Circuit Judges*.

The petition for rehearing filed by appellants in the above entitled case having been submitted to the judges who participated in the decision of this court and to all other available circuit judges of the circuit in regular active service, and no judge who concurred in the decision having asked for rehearing, and a majority of the circuit judges of the circuit in regular active service not having voted for rehearing by the court in banc, the petition for rehearing is denied.

BY THE COURT,

/s/ Carol Los Mansmann
Circuit Judge

JUL 26 1990

---

*Senior Judge Seitz voted only as to panel rehearing.

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA,

v.

GREEN DRUGS and
RAYMOND S. KAUFFMAN,

Defendants.

CA 89-173

Philadelphia, PA
August 7, 1989

TRANSCRIPT OF BENCH OPINION
BY THE HONORABLE EDWARD N. CAHN
UNITED STATES DISTRICT JUDGE

(Filed Sep. 20, 1989)

APPEARANCES:

For the Government:	DAVID F. McCOMB, ESQUIRE Assistant U.S. Attorney 3310 U.S. Courthouse Philadelphia, PA 19106
For the Defendants:	EARL G. KAUFFMAN, ESQUIRE The Bourse, Suite 900 Philadelphia, PA 19106
Audio Operator:	KRIS DRAGOTTA
Transcribed by:	DIANA DOMAN TRANSCRIBING P.O. Box 67 Audubon, NJ 08106 (609) 547-2506

Proceedings recorded by electronic sound recording; transcript produced by transcription service.

BENCH OPINION

THE COURT: Before the Court is a complaint brought by the United States of America as plaintiff against Green Drugs and Raymond S. Kauffman for civil penalties under the Controlled Substances Act. Under the Act, the defendants are required to make, keep and disclose to the Drug Enforcement Administration accurate records of receipts and dispositions of Schedule II controlled substances. The individual defendant is the owner and manager of Green Drugs which operates three retail pharmacies in the City of Philadelphia. Under the statute, he also is responsible for record keeping at the pharmacies in regard to Schedule II substances.

In October of 1986, the Drug Enforcement Administration identified the fact that Green Drugs was one of the largest purchasers of Prelucin, Percocet and Percodan in the Commonwealth of Pennsylvania. Pursuant to its diversion plan, the Drug Enforcement Administration decided to do a record check at Green Drugs. The record check disclosed shortages in the records for 2,752 Preludin tablets, 4,798 Percodan tablets and 1,902 Percocet tablets. The Government seeks a $25,000 civil penalty in regard to each of the aforesaid three shortages.

The defendant has aggressively defended against the charges brought by the Government. The defendants first urge that there were two serious mistakes in the computation made by the Drug Enforcement Administration. In one instance, 1,000 tablets of Percodan were charged to the defendants in error. In another instance, prescriptions for these Schedule II substances were taken by Drug

Enforcement Administration agents in regard to a criminal matter brought against a Philadelphia physician. Consequently, the defendants urge that the record tabulation of the Drug Enforcement Administration is more deficient than their own record keeping.

The second line of defense by the defendants is that after the adjustments for the Government's errors, the percentage of error is relatively minor ranging from less than one percent to something under five percent. The defendants have called an expert witness whose opinion is that deviations under five percent fall within the realm of human error. I accept that opinion, but that does not win the day for the defendants.

Congress in its wisdom has imposed strict liability on retail pharmacists to account for Schedule II substances. Even if the failure to account accurately is a result of inadvertence, liability may attach to the pharmacist. In this situation, I find as a fact that the deficits in the record keeping are inadvertent and innocent. In fact, the Government does not contend otherwise. What the Government contends is that innocent and inadvertent mistakes are still subject to civil penalty because Congress has decreed as a matter of public policy that pharmacists must at their peril account for Schedule II substances. I believe that I must follow congressional dictates in this regard, but I also find that the Court has discretion to temper the penalty in a situation such as this where the defendants have acted innocently of any intent to violate the law.

Another reason for being lenient with the defendants is that the defendants have taken adequate and aggressive steps to rectify the deficits in their record keeping. This fact will accrue to their benefit.

Consequently, I hold that modest civil penalties should be imposed in this case on the basis that the retail pharmacy industry must recognize its responsibility for the record keeping duties imposed by Congress. I therefore will impose civil penalties on the defendants in the amount of $2,000 on Count 1, $2,000 on Count 2 and $2,000 on Count 3. I am hopeful that this decision will disappoint both the plaintiff and the defendants. The plaintiffs will be disappointed because the United States Attorney's Office has asked for the maximum civil penalties of $25,000 on each count. I think that request is way out of line considering the errors of the plaintiff in maintaining its own records in regard to this investigation. The defendants will be disappointed because they ask the Court to nullify the Government's request because of the good faith they exhibited. While I agree that the defendants acted in good faith, I think Congress has decreed that good faith is not a defense to inadequate record keeping and therefore some penalty is due to motivate these defendants to continue to make every reasonable effort to account for controlled substances and to encourage other pharmacies to do the same.

Judgment will be entered in favor of the Government against both defendants in the amount of $6,000 plus costs.

CERTIFICATION

"We certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter."

/s/ Diana Doman
DIANA DOMAN

/s/ Kathleen Nazarok
KATHLEEN NAZAROK

9-22-89
DATE

§ 827. Records and reports of registrants

Inventory

(a) Except as provided in subsection (c) of this section–

(1) every registrant under this subchapter shall, on May 1, 1971, or as soon thereafter as such registrant first engages in the manufacture, distribution, or dispensing of controlled substances, and every second year thereafter, make a complete and accurate record of all stocks thereof on hand, except that the regulations prescribed under this section shall permit each such biennial inventory (following the initial inventory required by this paragraph) to be prepared on such registrant's regular general physical inventory date (if any) which is nearest to and does not vary by more than six months from the biennial date that would otherwise apply;

(2) on the effective date of each regulation of the Attorney General controlling a substance that immediately prior to such date was not a controlled substance, each registrant under this subchapter manufacturing, distributing, or dispensing such substance shall make a complete and accurate record of all stocks thereof on hand; and

(3) on and after May 1, 1971, every registrant under this subchapter manufacturing, distributing, or dispensing a controlled substance or substances shall maintain, on a current basis, a complete and accurate record of each such substance manufactured, received, sold, delivered, or otherwise disposed of by him, except that this paragraph shall not require the maintenance of a perpetual inventory.

Availability of records

(b) Every inventory or other record required under this section (1) shall be in accordance with, and contain such relevant information as may be required by, regulations of the Attorney General, (2) shall (A) be maintained separately from all other records of the registrant, or (B) alternatively, in the case of nonnarcotic controlled substances, be in such form that information required by the Attorney General is readily retrievable from the ordinary business records of the registrant, and (3) shall be kept and be available, for at least two years, for inspection and copying by officers or employees of the United States authorized by the Attorney General.

§ 842. Prohibited Acts B

Unlawful acts

(a) It shall be unlawful for any person–

(1) who is subject to the requirements of part C to distribute or dispense a controlled substance in violation of section 829 of this title;

(2) who is a registrant to distribute or dispense a controlled substance not authorized by his registration to another registrant or other authorized person or to manufacture a controlled substance not authorized by his registration;

(3) who is a registrant to distribute a controlled substance in violation of section 825 of this title;

(4) to remove, alter, or obliterate a symbol or label required by section 825 of this title;

(5) to refuse or fail to make, keep, or furnish any record, report, notification, declaration, order or order form, statement, invoice, or information required under this subchapter or subchapter II of this chapter;

(6) to refuse any entry into any premises or inspection authorized by this subchapter or subchapter II of this chapter;

(7) to remove, break, injure, or deface a seal placed upon controlled substances pursuant to section 824(f) or 881 of this title or to remove or dispose of substances so placed under seal;

(8) to use, to his own advantage, or to reveal, other than to duly authorized officers or employees of the United States, or to the courts when relevant in any judicial proceeding under this subchapter or subchapter II of this chapter, any informa-

COMPREHENSIVE DRUG ABUSE PREVENTION AND CONTROL ACT OF 1970

For Legislative History of Act, see p. 4566

PUBLIC LAW 91-513; 84 STAT. 1236
[H. R. 18583]

An Act to amend the Public Health Service Act and other laws to provide increased research into, and prevention of drug abuse and drug dependence; to provide for treatment and rehabilitation of drug abusers and drug dependent persons; and to strengthen existing law enforcement authority in the field of drug abuse.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That:

This Act may be cited as the "Comprehensive Drug Abuse Prevention and Control Act of 1970".

TABLE OF CONTENTS

RECORDS AND REPORTS OF REGISTRANTS

Sec. 307. (a) Except as provided in subsection (c)–

(1) every registrant under this title shall, on the effective date of this section, or as soon thereafter as such registrant first engages in the manufacture, distribution, or dispensing of controlled substances, and every second year thereafter, make a complete and accurate record of all stocks thereof on hand, except that the regulations prescribed under this section shall permit each such biennial inventory (following the initial inventory required by this paragraph) to be prepared on such registrant's regular general physical inventory date (if any) which is nearest to and does not vary by more than six months from the biennial date that would otherwise apply;

(2) on the effective date of each regulation of the Attorney General controlling a substance that immediately prior to such date was not a controlled substance, each registrant under this title manufacturing, distributing, or dispensing such substance shall make a complete and accurate record of all stocks thereof on hand; and

(3) on and after the effective date of this section, every registrant under this title manufacturing, distributing, or dispensing a controlled substance or substances shall maintain, on a current basis, a complete and accurate record of each such substance manufactured, received, sold, delivered, or otherwise disposed of by him, except that this paragraph shall not require the maintenance of a perpetual inventory.

(b) Every inventory or other record required under this section (1) shall be in accordance with, and contain

such relevant information as may be required by, regulations of the Attorney General, (2) shall (A) be maintained separately from all other records of the registrant, or (B) alternatively, in the case of nonnarcotic controlled substances, be in such form that information required by the Attorney General is readily retrievable from the ordinary business records of the registrant, and (3) shall be kept and be available, for at least two years, for inspection and copying by officers or employees of the United States authorized by the Attorney General.

ORDER FORMS

Sec. 308. (c) (1) Every person who in pursuance of an order required under subsection (a) distributes a controlled substance shall preserve such order for a period of two years, and shall make such order available for inspection and copying by officers and employees of the United States duly authorized for that purpose by the Attorney General, and by officers or employees of States or their political subdivisions who are charged with the enforcement of State or local laws regulating the production, or regulating the distribution or dispensing, of controlled substances and who are authorized under such laws to inspect such orders.

(2) Every person who gives an order required under subsection (a) shall, at or before the time of giving such order, make or cause to be made a duplicate thereof on a form to be issued by the Attorney General in blank in accordance with subsection (d) and regulations prescribed by him pursuant to this section, and shall, if such order is accepted, preserve such duplicate for a period of two

years and make it available for inspection and copying by the officers and employees mentioned in paragraph (1) of this subsection.

DRUG ABUSE CONTROL AMENDMENTS OF 1965

For Legislative History of Act, see p. 1895

PUBLIC LAW 89-74; 79 STAT. 226

[II. R. 2]

An Act to protect the public health and safety by amending the Federal Food, Drug, and Cosmetic Act to establish special controls for depressant and stimulant drugs and counterfeit drugs, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That:

This Act may be cited as the "Drug Abuse Control Amendments of 1965".

FINDINGS AND DECLARATION

Sec. 2. The Congress hereby finds and declares that there is a widespread illicit traffic in depressant and stimulant drugs moving in or otherwise affecting interstate commerce; that the use of such drugs, when not under the supervision of a licensed practitioner, often endangers safety on the highways (without distinction of interstate and intrastate traffic thereon) and otherwise has become a threat to the public health and safety, making additional regulation of such drugs necessary regardless of the intrastate or interstate origin of such drugs; that in order to make regulation and protection of interstate commerce in such drugs effective, regulation of intrastate commerce is also necessary because, among other things, such drugs, when held for illicit sale, often do not bear labeling showing their place of origin and because in the form in which they are so held or in which

they are consumed a determination of their place of origin is often extremely difficult or impossible; and that regulation of interstate commerce without the regulation of interstate commerce in such drugs, as provided in this Act, would discriminate against and adversely affect interstate commerce in such drugs, session of a depressant or stimulant drug in violation of this subsection (which is made a prohibited act by section 301(a) (3)), the United States shall have the burden of proof that the possession involved does not come within the exceptions contained in clauses (1) and (2) of the preceding sentence.

"(d) (1) Every person engaged in manufacturing, compounding, processing, selling, delivering, or otherwise disposing of any depressant or stimulant drug shall, upon the effective date of this section, prepare a complete and accurate record of all stocks of each such drug on hand and shall keep such record for three years. On and after the effective date of this section, every person manufacturing, compounding, or processing any depressant or stimulant drug shall prepare and keep, for not less than three years, a complete and accurate record of the kind and quantity of each such drug manufactured, compounded, or processed and the date of such manufacture, compounding, or processing; and every person selling, delivering, or otherwise disposing of any depressant or stimulant drug shall prepare or obtain, and keep for not less than three years, a complete and accurate record of the kind and quantity of each such drug received, sold, delivered, or otherwise disposed of, the name and address of the person, and the registration number, if any, assigned to such person by the Secretary pursuant to section 510(e), from whom it was received and to whom it

was sold, delivered, or otherwise disposed of, and the date of such transaction. No separate records, nor set form or forms for any of the foregoing records, shall be required as long as records containing the required information are available.

Remington's

PRACTICE OF PHARMACY

A treatise on the manufacturing, standardizing, and dispensing of pharmaceutical products, with biological and chemical properties, tests for purity, assays, uses, and doses; also a guide to the legal obligations of the pharmacist and the professional services rendered in helping to maintain community health

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1956

The Harrison or Federal Narcotic Law and Regulations

Registration – Persons already registered must *on or before July 1* of each year file application in the same manner for the renewal of their registration.

Inventories – An inventory on the reverse of Form 678 is required for each class except Classes 1 and 2.

(7) Recommendation. The recordkeeping provisions of the 1965 amendments should be amended to require that records must be segregated or kept in some other manner that enables them to be promptly identified and inspected.

RECORDS AND REPORTS

Existing law provides for inventories and recordkeeping with respect to all drugs subject to control under the Drug Abuse Control Amendments of 1965 and under the laws regulating narcotic drugs. The bill continues, and strengthens these requirements, as recommended by both the Prettyman Commission and the Katzenbach Commission, and requires that records be maintained either separately of all other records of the registrant or alternatively, in the case of nonnarcotic substances, be in such form that information required is readily retrievable from the ordinary business records of the registrant. As pointed out in a letter to the committee from the Office of the Deputy Attorney General, set forth hereafter in this report under the heading "agency reports", ordinary business records will frequently serve the purposes of this section, so long as the information required is readily retrievable through the use of red-line, asterisk, or other types of identification of items on invoices or other records.

Practicing physicians will be required to continue the recordkeeping required under existing laws, under which a physician is required to keep records of all narcotic

drugs which are dispensed to a patient (except by prescribing or administration) and, in case the physician is regularly engaged in charging his patients for nonnarcotic controlled substances he must keep records of all such substances dispensed to them.

U.S. Department of Justice
Drug Enforcement Administration

Pharmacist's Manual
An Informational Outline of the
Controlled Substances Act of 1970
Revised April 1986

Records

Every pharmacy engaged in handling controlled substances must keep complete and accurate records of all receiving and dispensing transactions. All such records shall be maintained for a period of two years.

All inventories and records of controlled substances in Schedule II must be maintained separately from all other records of the registrant. All inventories and records of controlled substances in Schedules III, IV, and V must be maintained separately or must be in such form that they are readily retrievable from the ordinary professional and business records of the pharmacy.

All records pertaining to controlled substances must be made available for inspection and copying by duly authorized officials of the Drug Enforcement Administration.

When a registrant first engages in business and every two years thereafter, a complete and accurate inventory of all stocks of controlled substances on hand must be made. This inventory record shall be kept by the registrant for a period of two years. *Pharmacies are not required to submit a copy of the inventory to the Drug Enforcement Administration.* See inventory Requirements.

Inventory Requirements

The Controlled Substances Act (P.L. 91-513) requires each registrant to make a complete and accurate record every two years of all stocks of controlled substances on hand.

Biennial Inventory

Every two years following the date of the registrant's initial inventory, a new inventory must be taken. The information required on the biennial inventory is the same as that for the initial inventory. The biennial inventory date may be changed by the registrant to fit the regular general physical inventory date, if any, so long as the date is not more than six (6) months from the biennial date that would otherwise apply. The actual taking of the inventory should not vary more than four (4) days from the biennial inventory date. A registrant desiring to change the biennial inventory date must notify in advance the nearest DEA office of the date on which the inventory is to be taken.

When taking the inventory of Schedule II controlled substances, an exact count or measure must be made. When taking the inventory of Schedules III, IV, and V controlled substances, an estimated count may be made. If the container holds more than 1,000 dosage units, an exact count must be made if the container has been opened.

Newly Controlled Substances – occasionally a drug that has not been previously controlled will be placed in one of the drug schedules or a controlled substance will

be moved into a higher or lower schedule. In either of these cases, the drug must be inventoried as of the effective date of transfer, and this inventory added to the biennial inventory. Also see the section on Records.